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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,194	03/01/2000	LETTS L GORDON		3420
25270	7590	06/15/2006		
EDWARD D GRIEFF HALE & DORR LLP 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			EXAMINER	STOCKTON, LAURA LYNNE
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/516,194	GORDON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 March 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-4 and 117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-4 and 117 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

**Claims 2-4 and 117 are pending in the application.**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2006 has been entered.

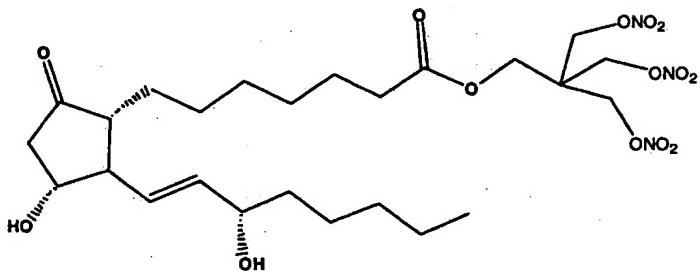
### ***Election/Restriction***

Applicants' election with traverse of Group II and the species of Example 11 (reproduced below) on pages

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52-54 of the instant specification, in the reply filed on October 15, 2004 was acknowledged in the previous Office Action.

**Example 11**



The requirement was deemed proper and was made FINAL in the previous Office Action. On April 15, 2005, Applicants petitioned the Restriction requirement of August 16, 2004.

On July 13, 2005, the Petition of the Restriction requirement of August 16, 2004 was granted to the extent that all of the compound groups (i.e., Groups I-XI) would be combined into one group, hereinafter known

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as modified Group I (claims 2, 3 and newly added claim 117, directed to compounds). The Petition grant also stated that an election of species was found to be proper and therefore, maintained and that the examiner is directed to follow the guidelines of M.P.E.P. 803.02. See bottom of page 4 and top of page 5 of the Petition grant of July 13, 2005.

The entire scope of the currently claimed subject matter of claims 2-4 and 117 has now been examined. Note, claim 4 has been rejoined with the elected invention and has now been examined. Applicant timely traversed the restriction (election) requirement in the reply filed on October 15, 2004.

***Response to Amendment***

The amendment filed March 29, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter

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into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The deleted material which is not supported by the original disclosure is as follows: the amendment to the specification at page 16, line 32 to page 17, line 4. Specifically, the deletion of "beraprost", "fluprostenol", "limaprost", "misoprost" and "viprostol" from the specification.

Applicant is required to add these compounds back into the specification, in the reply, if any, to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2-4 and 117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, under the definition of when R<sub>8</sub> and R<sub>9</sub>, taken together, the phrase "with the proviso that R<sub>1</sub> is an oxygen atom which is attached to the carbon atom at the position of the benzene ring defined by B" is indefinite since R<sub>1</sub> would not be directly attached to the benzene ring formed by R<sub>8</sub> and R<sub>9</sub>.

In claim 2, under the proviso in the definition of the K variable, the phrase "cycloalkyl mononitrate; a benzoic acid substituted benzyloxy mononitrate; the regioisomeric esters of glycerol dinitrate and oligomers thereof" makes claim 2 indefinite since three (3) nitrate groups must be present (see the proviso at the end of the claim).

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Since claim 3 is directed to a compound, having the phrase "a mixture thereof" makes claim 3 indefinite and should be deleted.

Claim 117 is indefinite because the claim names known compounds then uses the language "comprising at least one NO group", which is: (1) improper Markush language; and (2) confusing since the known compounds do not have any NO groups. It is suggested that claim 117 be re-written (see format of claim 3).

Claim 117 is indefinite because it would appear that something is missing in the phrase "unoprostone or, through an oxygen atom, a nitrogen atom or a sulfur atom" (see end of claim).

#### ***Allowable Subject Matter***

The elected species of Example 11 is allowable over the art of record.

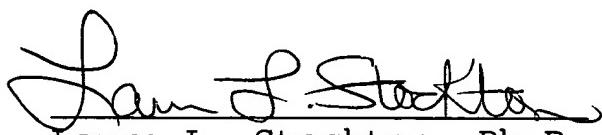
Any inquiry concerning this communication or earlier communications from the examiner should be

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directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

June 12, 2006